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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/443,072      | 11/18/1999  | BRIAN A. ROSENFELD MD | 483-001             | 6723             |

7590

08/07/2002

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EXAMINER

HARLE, JENNIFER I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3627

DATE MAILED: 08/07/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/443,072

Applicant(s)

ROSENFELD MD ET AL.

Examiner

Jennifer I. Harle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 11.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 15-27 are pending. Claim 15 corresponds to claim 1, claim 16 corresponds to claim 2, claim 17 corresponds to claim 3, claim 18 corresponds to 4, claim 19 corresponds to 5, claim 20 corresponds to claim 6, claim 21 corresponds to claim 7, claim 22 corresponds to 8, claim 23 corresponds to claim 9, claim 24 corresponds to claim 10, claim 25 corresponds to claim 11 (amended), claim 26 corresponds to claim 13, claim 27 corresponds to claim 14. Claims 15- 27 are rejected under 102(b), public use, as set forth in the previous rejection. Claims 21-22, 24, 26-27 are rejected under 102(b) and 103(a), as set forth in the previous rejection. It is noted that applicant did not specifically address any of the 103(a) arguments in his action. The previous final action, paper number 9 – mailed July 19, 2002 is withdrawn and replaced with this final action. Claims 15-27 are rejected and **made final**.

### ***Response to Arguments***

Applicant's arguments filed June 6, 2002 have been fully considered but they are not persuasive. Applicant argues that there was no public use and merely states that the activity was experimental use because "the present clinical trial or 'study' was clearly for the purpose of ascertaining whether remote monitoring of an ICU would provide adequate care to patients. The study had no commercial exploitation as it was performed by the Johns Hopkins University School of Medicine in the affiliated hospital. The study therefore clearly falls within this acceptable use especially when compared to the factors below." The Applicant then recites the factors (A)-(D) from *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1878); (E) from *Egbert v. Lippman*, 104 U.S. (1881); (F) from

*International Tooth Crown Co. v. Gaylord*, 140 U.S. 55 (1891); (G) from *Robbins Co. v. Lawrence Mfg. Co.*, 178 USPQ 577, 583 (9<sup>th</sup> Cir. 1973); and (H) from *TP Labs., Inv. V. Professional Positions, Inc.*, 220 USPQ 577, 582, 724 F.2d 965, 971 (Fed. Cir. 1984) as set forth in the MPEP. The applicant provides one sentence lines of reasoning to support his allegations that these factors weigh in his favor but no documentation, records, affidavits or other proffers of proof. In fact, for factors (G) and (H) no allegation were made that these applied to the inventors nor was any documentation, records, affidavits or other proffers of proof provided.

The examiner will provide a brief review of the *prima facie* case establishing prior/public use and Applicant's failure to come forward with convincing evidence to counter that showing in light of the entire surrounding circumstances. See *TP Labs., Inc. v. Professional Positions, Inc.*, 220 USPQ 577, 724 F.2d 965, (Fed. Cir. 1984).

***Response to Claims Rejections – 35 U.S.C. § 102(b)***

Applicant argues that none of the cited references disclose any public use or sale prior to the critical date. Applicant defines the critical date as being June 23, 1998 based upon the provisional application 60/141,520, filed June 23, 1999 as claimed in the Supplemental Declaration filed April 12, 2002. However, the Oath/Declaration is defective.

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The Supplemental Oath Declaration and Power of Attorney identifies two different filing dates for the Application, one in the header of November 18, 1999 and one in the body of November 19, 1999.

***Assuming Arguendo Oath/Declaration is Corrected/Not Defective***

If the critical date is accepted as being June 23, 1998, there is still a 102(b) date disclosing public use prior to the critical date. There are two facts, which support the 102(b) public use date. First, the study was approved by the Johns Hopkins Medical Institution's Joint Committee on Clinical Investigation and the approval of funding to purchase the Telemedical equipment from Healthcare Interchange of St. Louis, MO.<sup>1</sup> Second, the study began on September 1, 1996. Either of these are first overt acts, which predate the critical date and hence are construed as the 102(b) date because "the present study evaluated the feasibility of remote ICU management by evaluating whether instituting 24-hr remote management of ICU patients would improve clinical outcomes and reduce costs in an ICU without continuous on-site intensivist care," (Rosenfeld, Critical Care Medicine, 2000, Vol. 28, No. 12, pg. 3926), the critical date would include at the least the inception of the "study", which would include the baseline periods.

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<sup>1</sup> The study approval would have been preceded by a study proposal that set forth all the parameters for the study including monitoring patients in a plurality of ICU's/healthcare locations by communicating the information from the patient monitoring to at least one command center over a first network, receiving and analyzing the information; providing guidance from the command center to the plurality of ICU's to take action regarding patient care, and further comprises an intensivist reviewing decisions 24/7 with the support algorithms that provide guidance for treating a plurality of critical care conditions.

*Argument of No Public Use Not Persuasive*

A. *Argument Acceptable Activity, i.e. No Public Use – Experimental Use Not Persuasive*

As set forth in *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877), public use is the starting place for analysis of any case involving experimental use, reasoning that public use is negated if experimental use can be shown. However, once a *prima facie* case of experimental use is made the patent owner [applicant] must be able to point to or come forward with convincing evidence to counter that showing. *Strong v. General Electric Co.*, 168 USPQ 8, 9, 434 F.2d 1042, 1044 (5<sup>th</sup> Cir. 1970); See also *Harrington Mfg. Co., Inc. v. Powell Mfg.*, 2 USPQ2d 1364, 815 F.2d 1478, 1482 (Fed. Cir. 1986)(stating that on summary judgment, once a *prima facie* case for public use has been established, the patentee [applicant] must come forward with some evidence that there is a genuine issue of material fact on the issue of public use).

Applicant argues that alleged public use revolves around the “clinical trial” (i.e. study) described in Crit. Care Med. 2000, 28:12 but does not involve monitoring “a plurality of health care locations” (claim 14) or “plurality of ICUs” (claim 25) and as such that the clinical trial monitoring of a single surgical ICU was not a use of the presently claimed invention. Plurality of health care locations is not defined in the specification. The examiner has interpreted this phrase to mean the 10 different rooms utilized in the first 16 week study. Each ICU room was in a particular portion of space chosen for that ICU in other words it is the place where each ICU was located.<sup>2</sup> Therefore, there was more than

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<sup>2</sup> Roget's II: The new Thesaurus, Third Edition, 1995, <http://www.bartleby.com/62/23/L0922300.html>, printed July 16, 2002.

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one, the 10 ICUs located in a plurality of health care locations, as they were located in different rooms/locations in the hospital. Applicant further argues that the clinical trial include a single "10 bed surgical ICU." The specification defines ICU as contains identifying information for an ICU at a hospital (pg. 19, line 16). The specification further defines ICU bed as contains the association for identifying which beds are in a given hospital and ICU patient location as provides the association between an ICU and a patient and identifies where a patient is located within an ICU in a particular hospital (pg. 19, lines 17-19). The article teaches that there were multiple ICU environments (including elective and emergency surgical and trauma patients) and in this case "the ICU" was functioning as several or multiple ICUs, including a Medical ICU (MICU), Surgical ICU (SICU) and Trauma ICU.<sup>3</sup> The examiner interprets these environments to be multiple ICUs, i.e. different units. Therefore, the article inherently/implicitly teaches a monitoring patients in a plurality of ICU's as hospitals can have more than one ICU.

The applicant further argues that the basic test is that experimentation must be the primary purpose and that " a use ... is experimental for the purposes of section 102(b) if it represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose." See MPEP 2133.03(e); permitted activity; Experimental Use *quoting LaBounty Mfg. V. United States Int'l Trade Comm'n*, 22 USPQ2d 1025, 1028, 958 F.2d 1066, 1071 (Fed. Cir. 1992)(*quoting Pennwalt Corp. v. Akzona, Inc.*, 222 USPQ 833, 838, 740 USPQ 1573, 1581 (Fed. Cir. 1984)). Applicant applies this test to state that "by

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<sup>3</sup> MHS Optimization and Population Support Center Glossary Terms and Abbreviations, [http://www.tricare.osd.mil/mhsophsc/mhs\\_supportcenter/Glossary/lg.htm](http://www.tricare.osd.mil/mhsophsc/mhs_supportcenter/Glossary/lg.htm), November 13, 2001, printed July 16, 2001. Intensive Care Unit types include Medical ICU, and Surgical ICU. See also, Los Angeles Count +University of Southern California Trauma Surgery and Critical Care for Trauma ICU.

definition the present clinical trial or "study" was clearly for the purpose of providing adequate care to patient." (pg. 11- Applicant's Response Under 37 CFR 1.1111).

The examiner respectfully disagrees. Critical Care Medicine specifically states that the study evaluated the feasibility of whether remote ICU management of ICU patients by trained intensivists would **improve** clinical outcomes and **reduce** costs in an ICU without continuous on-site intensivist care (pg. 3926). Thus, it was not a clinical trial as set forth by applicant to see if telemedicine would work with patients utilizing intensivist in an ICU environment but rather a feasibility study. A feasibility study is conducted in business to determine the likelihood that a proposed product will fulfill the objectives of a particular investor, i.e. whether there would be improved clinical outcomes, i.e. better results, and reduced costs.<sup>4</sup> Neither of these are experimental use nor are they the experimental intended purposes as set forth by Applicant.

In fact, the feasibility study appears to be an exception to the experimental use in the form of market testing. See *In re Smith and McLaughlin*, 218 USPQ 976, 983, 714 F.2d 1127, 1134 (Fed. Cir. 1983). It appears to be an attempt to gauge whether consumer demand for his invention by proving the benefits. Any experimental use claimed appears to be merely incidental and subsidiary. Applicant has not presented any objective evidence indicating that this alleged testing was for experimental use. *Id.* (citing *Robbins Co. v. Lawrence Manufacturing Co.*, 178 USPQ 577, 581, 482 F.2d 426, 431 (9<sup>th</sup> Cir. 1973). Cf. *In re. Theis*, 204 USPQ 188, 193, 610 F.2d 786, 792 (CCPA 1979)).

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<sup>4</sup> Jack P. Friedman, Dictionary of Business Terms, Third Edition, 2000, pg. 247.



Thus, the use appears not to be experimental, had a commercial component, and therefore not an acceptable use, which would negate public use.

B. Nature of the Invention was Such that Any Testing Had to be to Some Extent Public

As set forth above, the testing was public and not just to some extent. Applicant admits that the "study" was performed by Johns Hopkins University School of Medicine in an affiliated hospital. Not once does Applicant allege that anyone, patients, visitors, employees of the hospital (doctors, nurses, technicians, volunteers, etc.), employees of Johns Hopkins University/Medical Institution, Healthcare Exchange Interchange employees, the outside intensivists and support staff, or any others were under any limitation, restriction or obligation of secrecy to the inventor. Thus, this factor appears to weigh strongly in favor of public use as well. See *In re Smith*, 218 USPQ 976, 983 (Fed. Cir. 1983) (citing *Egbert v. Lippman*, 104 U.S. 333, 336 (1881) (describing 'public use' as including any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor)).

C. Testing Had to Be for a Substantial Period of Time

The examiner concedes that the telemonitoring occurred for a sixteen week period and that there were two baseline periods. Applicant has not provided anything other than an assertion that 16 weeks is a sufficient period to gather data. No break down is provided as to how long different patients with different conditions remained in the ICU and whether certain conditions might be reflected differently in the improvement and cost analysis. Moreover, the ICU allegedly excluded cardiac and transplant surgery patients. Yet baseline 1 has 2 primary system failures from transplants and all the statistics encompass

cardiovascular primary system failures. This raises some questions about the validity of the study and the periods of time. Thus, this factor is indeterminant and not given any real weight.

D. Testing Was Not Conducted Under the Supervision and Control of the Inventor

Applicant alleges that the inventors participated in and supervised the trial.

However, no specifics are given, just the general allegation. The article is written by eight individuals. The study was approved by Johns Hopkins Medical Institution's Joint Committee on Clinical Investigation. The examiner believes that the inventors along with Todd Dorman and Peter Pronovost participated in the trial by acting as the four intensivists and that they, along with Health Interchange personnel trained on-site care givers.

However, there is nothing to indicate that the intensivists performed anything other than medical duties under the auspices of Johns Hopkins. There is nothing to indicate that they supervised the study, i.e. checked on the equipment/system, had any supervision over the other intensivists, reviewed any reports by the other intensivists or reports on the data as it was submitted, extrapolated or acquired, etc. or that they had any control at all over the study. The study was approved by Johns Hopkins. There is no indication that the inventors were receiving any reports or updates as to the status of the study. The inventors were employees of Johns Hopkins and as such were merely a pair of hands under the control of Johns Hopkins. There is no indication that Johns Hopkins or the affiliate hospital was required to provide any reports to the inventors. The fact that the data was provided, classified and abstracted by an independent group, lead by Haya Rubin, and the reports computed by APACHEIII computer tends to support the fact that the

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study supervision and control was not in the hands of the inventors. There appears to be no consensual agency relationship in which Johns Hopkins or the affiliate hospital agreed to act upon the instruction of the principals (inventors) nor does it appear that any limitations were placed upon Johns Hopkins or the affiliate hospital. See *In re Hamilton*, 11 USPQ2d 1890, 1894, 1895 (stating that the invention must be kept under the control of the inventor). In fact, it appears to be the other way around, the study could be discontinued, the scope changed or reevaluated, at any time by Johns Hopkins or the affiliate hospital.

Thus, this factor appears to weigh against experimental use.

- (E) The Inventors regularly inspected the invention during the period of experimentation.

Applicant did not address this factor and it is deemed to have waived any arguments addressing this factor. Additionally, the article specifically states that study intensivists (two of which were the inventors) never came to the hospital to care for patients. Additionally, there is nothing in the article that states that the inventors inspected the system or that they inspected the records or logs of the other two intensivists.

Thus, this factor appears to weigh against experimental use.

*Response to Applicant's Other Significant Criteria*

- A. Extent of Any Obligations or Limitation Placed on a user during a Period of Experimental Activity, As Well As the Extent of Any Testing Actually Performed (Egbert v. Lippmann, 104 U.S. 333 (1881))

Applicant argues that this factor was present since the trial was limited in scope (a single surgical ICU) and time. It is not clear how these are obligations or limitations placed

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on a user during experimental activity. There is nothing to indicate that the user, i.e. Johns Hopkins or the affiliate hospital, was restricted to implementation in a single ICU or time frame, and in fact the examiner has argued that in reality it is multiple ICUs. Nor is there anything to indicate that the user was required to remove the system or not to continue with the method after the sixteen week period. The article merely states that the affiliate hospital chose to go to a full time intensivist system. Not that they were obligated to do so or that they were limited to doing so. Nor does the article state that the affiliate hospital was precluded from using the system in their new neurologic ICU. Applicant does not present any facts or data to support any obligations or limitations placed on the user, i.e. the affiliate hospital or Johns Hopkins.

Thus, this factor is not persuasive as presented and appears to weigh against experimental use.

B. Length of Time and Number of Cases in Which Experimental Activity Took Place, Viewed in Light of What was Reasonably Necessary for an Alleged Experimental Purpose (International Tooth Crown Co. v. Gaylord, 140 (US 55 (1891))

Applicant reiterates the arguments set forth under the arguments for sections A. and C. of Argument of No Public Use Not Persuasive. Therefore examiner refers applicant to those sections for the rebuttal arguments. As those arguments were not persuasive before, they are not deemed persuasive in this instance.

Thus, this factor appears to weigh against experimental use.

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- C. Explicit or Implicit Obligations Placed upon a User to Supply an Inventor with the Results of Any Testing Conducted During an Experimental Period and the Extent of Inquiry Made By the Inventor Regarding the Testing (Robbins Co. v. Lawrence Mfg. Co., 178 USPQ 577, 583 (9<sup>th</sup> Cir. 1973))

Applicant argues that the study was solely to collect patient data to compare remote-monitored patient care with ordinary patient care and involved the doctor-patient relationship. This argument has nothing to with any explicit or implicit obligations placed upon a user to supply an inventor with the results of any testing conducted during an experimental period and the extent of inquiry made by the inventor regarding the testing. As discussed above, there do not appear to be any explicit or implicit obligation placed upon Johns Hopkins or the affiliated hospital to supply the inventor with the results of any testing conducted. The study was approved by Johns Hopkins. There is no indication that the inventors were receiving any reports or updates as to the status of the study. The inventors were employees of Johns Hopkins and as such were merely a pair of hands under the control of Johns Hopkins. There is no indication that Johns Hopkins or the affiliate hospital was required to provide any reports to the inventors. The fact that the data was provided, classified and abstracted by an independent group, lead by Haya Rubin, and the reports computed by APACHEIII computer tends to support the fact that the study supervision and control was not in the hands of the inventors. Critical Care Medicine, pg. 3926. There appears to be no consensual agency relationship in which Johns Hopkins or the affiliate hospital agreed to act upon the instruction of the principals (inventors) nor does it appear that any limitations were placed upon Johns Hopkins or the affiliate hospital. See *In re Hamilton*, 11 USPQ2d 1890, 1894, 1895 (stating that the

invention must be kept under the control of the inventor). In fact, it appears to be the other way around, the study could be discontinued, the scope changed or reevaluated, at any time by Johns Hopkins or the affiliate hospital. Moreover, the article was co-authored by eight individuals. It is unclear who actually wrote what sections of the article, i.e. the sections concerning reporting and data analysis, but it would appear to be based upon the Quality Care Research – Johns Hopkins University or Health Policy and Management and their backgrounds are suited for the type of statistical analysis. None of the people listed from these Departments are the inventors.

Moreover, the article specifically states that study intensivists (two of which were the inventors) never came to the hospital to care for patients, nor is there anything in the article that states that the inventors inspected the system or that they inspected the records or logs of the other two intensivists, or that they requested/inquired to see any of the data as it was being extrapolated, input or output for use by APACHE III or the anyone utilizing the computer system to generate reports.

As previously stated, applicant provides no documentation, records, affidavits or other proffers of proof. Thus, this factor appears to weigh against experimental use.

- D. A Doctor-Patient Relationship Where the Inventor/Doctor Conduct the Experimentation (TP Labs, Inc. v. Professional Positions, Inc. 220 USPQ 577, 582, 724 F.2d, 965, 971 (Fed. Cir. 1984)

Applicant argues again that the study was solely to collect patient data to compare remote-monitored patient care with ordinary patient care and involved the doctor-patient relationship since doctors conducted the study with the patients. Once again applicants provide not provided documentation, records, affidavits or other proffers of proof. As

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argued above this case is a feasibility study and not experimental use and thus the use was not solely for the reasons Applicant set forth. Additionally, this phrase is not explicitly stated in the TP Labs case and TP Labs can be factually distinguished from applicant. TP Labs, Inc. involved orthodontal devices and their function must be shown to others for routine maintenance. Additionally, there were only three devices used during the critical period. Here there were over 201 patients exposed to the telemonitoring and 628 patients involved in the whole study. The inventor in TP Lab, Inc. was one of the dentists in the professional practice that examined the orthodontia devices and an officer, i.e. one of the owners of TP Labs. In other words, he had a position of authority and control in both the dental practice and TP Labs. The inventor, Kesling, assigned the invention to TP Labs. None of these facts apply to applicants. Applicants were employees of Johns Hopkins and the invention was never assigned to them. Moreover, the two businesses in TP Labs shared a small building and employed the same office manager. Johns Hopkins is a large institution and the study was conducted in an affiliated hospital, i.e. there were a plethora of people involved. The key phrase in TP Labs, Inc. is a "pledge of confidentiality is indicative of the inventor's continued control which is established inherently by the dentist-patient relationship of the parties. Nothing in the inventor's use of the device on his patients (or the transfer to them) is inconsistent with experimentation." In Applicant's case, as discussed above there is nothing indicative of the inventors' continued control on which to rely to establish that it is inherent to the doctor-patient relationship of the parties. In this case, the system/method was for use between a hospital and third party intensivists. The patients were benefited but not in the same way as the orthodontic device. The orthodontic

device was sold to the patients. The 24/7 remote monitoring/telemedicine by intensivists was to be sold/subscribed to by the hospitals not the patients. Thus, this case is distinguishable on several fronts and applicants argument is not deemed persuasive.

On the facts of the case, this factor appears to weigh against experimental use.

### ***Conclusion***

As, the applicant provides one sentence lines of reasoning to support his allegations that these factors weigh in his favor but no documentation, records, affidavits or other proffers of proof and for factors (G) and (H) provided no specific allegations that these factors applied to the inventors (including providing any documentation, records, affidavits or other proffers of proof), all of the factors appear to weigh against a finding of experimental use and the examiner upholds the rejection and makes it **final**.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is 703.306.2906. The examiner can normally be reached on Monday through Thursday, 6:00 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P. Olszewski can be reached on 703.305.9643. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

jih  
August 5, 2002

  
Richard Chilcot  
Assistant Patent Examiner  
Technology Center 200  
3627